II. REMARKS/ARGUMENTS

A. Substance Of Interview

In accordance with the provisions of 37 CFR 1.133, Applicants herein make of record the substance of the telephone interview conducted on October 25, 2007, between Applicants' attorneys, Oleg Ioselevich, Clifford M. Davidson and Phillip C. Strassburger, and Examiner Jon D. Epperson.

During the interview, proposed amendments to claim 38 were discussed in view of rejections made and the reference cited in the Office Action dated August 21, 2007. In particular, the teachings of U.S. Patent No. 4,569,937 to Baker et al. were explained.

Applicants thanks the Examiners for agreeing to the telephone interview, and respectfully request that the substance of interview be made of record.

B. Status of claims

Claim 38 has been amended without prejudice. Support for the amendment can be found, e.g., on page 12, line 27; page 24, line 31 to page 25, line 31 of the original specification and in original claims 49 and 50. Applicants respectfully note that that this change is not made in view of the cited references and is done without prejudice to the scope of coverage of the present case or the Applicant's ability to file a broader claim in a further continuation application.

New claims 53-62 have been added. Support for new claims 53, 56 and 61 can be found, e.g., on page 34, lines 11-23 of the original specification. Support for new claims 54 and 56 can be found, e.g., on page 22, lines 5-22 of the original specification. Support for new claim 55 can be found, e.g., in original claims 38, 49 and 50, on page 24, line 31 to page 25, line 31 of the original specification. Support for new claims 58 and 59 can be found, e.g., on page 25, lines 16-17 of the original specification. Support for new claim 60 can be found, e.g., on page 11 of the original specification. Support for new claim 62 can be found, e.g., on page 38, line 31

Claims 49 and 50 have been cancelled without prejudice in this amendment. Claims 1-37, 39-46 and 51-52 were previously canceled without prejudice.

Claims 38, 47, 48, and 53-62 are currently pending. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

C. Claim Rejections under 35 U.S.C. § 103(a)

In the Office Action, claims 38, 47, 48, 51, and 52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,569,937 to Baker et al. in view of Furst, D.E., "Meloxicam: Selective COX-2 inhibition in clinical practice", *Seminars in Arthritis and Rheumatism*, 26(1); pp. 21-27 (June 1997).

In response, Applicants submit that claim 38 has been amended without prejudice to recite that dosage forms utilized in the method of claim 38 comprises "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours or longer".

Applicants further submit that the combination of the Baker patent and the Furst reference does not teach or suggest a dosage which contains oxycodone, meloxicam, and "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours or longer" as recited in claim 38.

With regard to the Examiner's statement that substitution of ibuprofen with meloxicam "would have led to the predictable results ... because it was well known in the art that both drugs inhibit the same COX 1/2 receptors to produce similar results," Applicants respectfully note that although ibuprofen and meloxicam may both act on COX-1 and COX-2 receptors, the specificity of ibuprofen and meloxicam for these receptors is different and these receptors are located in different parts of the body. See, e.g., Table 1 of the present specification (showing that COX-

1/COX-2 ratio for ibuprofen is 0.067 and that COX-1/COX-2 ratio for meloxicam is 13). Therefore, Applicants submit that, because COX-1/COX-2 ratios of meloxicam and ibuprofen are significantly different, one skilled in the art, at the priority date of the present application, would not know what the exact result would be if ibuprofen was substituted with meloxicam in the Baker patent. In this regard, Applicants agree with the Examiner's determination that "[t]here's no evidence to suggest that Baker et al. knew anything about the benefits of meloxicam." See Office Action, page 20, second full paragraph.

In view of this information, it is respectfully requested that the Examiner reconsider the arguments presented in the response filed on May 30, 2007, herein incorporated by reference.

For the foregoing reasons, Applicants submit that the combined teachings of the Baker patent and the Furst reference would not have prompted the skilled person to modify the teachings of the Baker patent to arrive at a dosage which contains oxycodone, meloxicam, and "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours or longer" as recited in claim 38.

Accordingly, withdrawal of the rejection is respectfully requested.

With regard to new claim 55, Applicants respectfully note that the combination of the cited references does not teach or suggest a dosage form which "comprises (a) said meloxicam in immediate release form and (b) said oxycodone in sustained release form, said oral dosage form further comprising a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect of said oxycodone for at least 12 hours or longer," as recited in claim 55.

In the Office Action, claims 38 and 47-52 were rejected under U.S.C. 103 (a) over Baker et al. in view of in view of Furst, U.S. Patent No. 5,472,712 to Oshlack et al. (Oshlack I), U.S.

Patent No. 6,294,195 to Oshlack et al. (Oshlack II) and PCT Publication No. WO 97/25988 to Iyengar et al.

In response, Applicants submit that the combination of the cited references would not have prompted the skilled person to modify the teachings of the Baker patent to arrive at a dosage form which contains oxycodone, meloxicam, and "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours or longer" as recited in claim 38, at the very least, because one skilled in the art, at the priority date of the present application, would not have expected that substitution of ibuprofen with meloxicam would produce the same result.

Applicants further submit that Oshlack I, Oshlack II and Iyengar, even if properly combinable (a position which is refuted), fail to cure the deficiencies of the Baker patent and the Furst reference, as neither of the cited references describes a dosage form which contains oxycodone, meloxicam, and "a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect for about 12 hours or longer" as recited in claim 38" as recited in claim 38. Further, none of the cited references provides a direct comparison of the effects of ibuprofen and meloxicam in the body.

For the foregoing reasons, Applicants submit that the combination of the cited references does not render the present claims obvious and respectfully request removal of the rejection.

With regard to new claim 55, Applicants respectfully note that the combination of the cited references does not teach or suggest a dosage form which "comprises (a) said meloxicam in immediate release form and (b) said oxycodone in sustained release form, said oral dosage form further comprising a sustained release carrier in an amount such that said oral dosage form provides a therapeutic effect of said oxycodone for at least 12 hours or longer," as recited in claim 55.

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Oleg Ioselevich
Reg. No. 56,963

DAVIDSON, DAVIDSON & KAPPEL, LLC
Patents, Trademarks and Copyrights
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940